July 29, 2022

Medtronic Sofamor Danek USA
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K133904
Trade/Device Name: CD Horizon® Growth Rod Conversion Set
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: PGM

Dear Mr. Grant:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 25, 2014. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 21 CFR 888.3070.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ronald Jean, OHT6: Office of Orthopedic Devices, (301)796-5650, Ronald.Jean@fda.hhs.gov.

Sincerely,

Ronald P. Jean -S

Ronald P. Jean, Ph.D.
Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Medtronic Sofamor Danek USA
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K133904
Trade/Device Name: CD HORIZON® Growth Rod Conversion Set
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: PGM
Dated: January 17, 2014
Received: January 22, 2014

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133904

Device Name
CD HORIZON® Growth Rod Conversion Set

Indications for Use *(Describe)*
The CD HORIZON® Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The CD HORIZON® Growth Rod Conversion Set may be used with any cleared traditional CD HORIZON® Spinal System rod construct ranging in diameter from 3.5mm to 5.5mm, with the exception of PEEK Rod constructs. The CD HORIZON® Growth Rod Conversion Set may not be used with PEEK rods, SPIRE™ Spinous Process Plates, or Shape Memory Alloy (SMA) Staples.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Colin O'Neill

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

CD HORIZON® Growth Rod Conversion Set
510(k) Summary – K133904

FEB 2 5 2014

February 2014

Company: **Medtronic Sofamor Danek USA**
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Lee Grant
Distinguished Regulatory Affairs Advisor

Proprietary Trade Name: CD HORIZON® Growth Rod Conversion Set

Product Code: PGM

Regulation: Pre-Amendment Unclassified

Classification: Unclassified

Description:

The CD HORIZON® Growth Rod Conversion Set consists of a variety of connectors designed to convert a traditional fusion construct into a non-fusion growth enabling construct which can be surgically lengthened on a periodic basis as the patient grows. The CD HORIZON® Growth Rod Conversion Set components are manufactured from stainless steel and titanium alloy and are designed to interact with rod-based pedicle screw/hook constructs in which the rods range in diameter from 3.5mm to 5.5mm. The CD HORIZON® Growth Rod Conversion Set is specifically to be used with any traditional CD HORIZON® Spinal System (3.5mm to 5.5mm) fusion construct cleared for pediatric usage. The CD HORIZON® Growth Rod Conversion Set may not be used with PEEK Rods, SPIRE® Spinous Process Plates and/or Shape Memory Alloy (SMA) Staples. The CD HORIZON® Growth Rod Conversion Set is limited to a posterior approach.

Indications for Use:

The CD HORIZON® Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The

CD HORIZON® Growth Rod Conversion Set may be used with any cleared traditional CD HORIZON® Spinal System rod construct ranging in diameter from 3.5mm to 5.5mm, with the exception of PEEK Rod constructs. The CD HORIZON® Growth Rod Conversion Set may not be used with PEEK Rods, SPIRE™ Spinous Process Plates, or Shape Memory Alloy (SMA) Staples.

Summary of the Technological Characteristics: The subject CD HORIZON® Growth Rod Conversion Set Spinal System has the same fundamental scientific technology as the predicate Harrington Spinal Rod System for the treatment of spinal deformities in a non-fusion manner. Additionally, the subject CD HORIZON® Growth Rod Conversion Set connectors are substantially equivalent to similar connectors previously cleared in the CD HORIZON® Spinal System (K121764, SE 08/21/12). No new implant materials, instruments or sterilization methods are being added to the system through this application.

Identification of Legally Marketed Devices: The CD HORIZON® Growth Rod Conversion Set is substantially equivalent to the Harrington Spinal Rod System. The Harrington Spinal Rod System has been designated as a pre-amendment non-fusion spinal construct designed to treat pediatric patients who require surgical intervention prior to age 10 for severe, progressive, life-threatening early-onset deformities.

Discussion of Supporting Information and Non-Clinical Testing: Testing previously performed on the CD HORIZON® Growth Rod Conversion Set to support fusion applications was provided to support usage for the aforementioned non-fusion indication. Additionally, comparisons were made to Harrington Rod System which FDA designated (09/11/13) as a pre-amendment device for non-fusion surgical correction of this treatment population.

Conclusion: The design features, materials used, manufacturing and sterilization methods are equivalent to the pre-amendment Harrington Spinal Rod System device used to treat early onset deformities including early-onset scoliosis in a non-fusion manner and to previously cleared connectors which are contained within the CD HORIZON® Spinal System (K121764).